

## **REMARKS**

Upon entry of this amendment, claims 1-104 constitute the pending claims in the present application. Among them, claims 1-27, 34-53, and 89-92 are directed to non-elected inventions and are withdrawn from further consideration. Applicants have canceled these claims without prejudice. Applicants reserved the rights to prosecute claims of the same or similar scopes in future applications.

Applicants note that the IDS has been considered by the Examiner.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

### Specification objections

The Office Action objects to the specification as containing amino acid sequences without sequence identifiers. Specifically, the Office Action points out that the amino acid sequences in the figures have not been amended to include sequence identifiers. Accordingly, Applicants have amended Figures 2 and 5 to include proper sequence identifiers, thereby obviating this objection. A new Figure 2 and a new Figure 5 are submitted herewith for review and approval by the Examiner.

In addition, Applicants have amended the corresponding figure legends to reflect the changes made. Reconsideration and withdrawal of the objections are respectfully requested.

### Claim objection

Claims 86 and 88 are objected to because the claims do not have sequence identifiers for the cysteine loops.

Applicants submit that these cysteine loops need not have sequence identifiers, since it is the *positions* of these cysteines, not the particular sequences between these cysteines, that are referred to in the claims. In other words, “cysteine loop Cys53-Cys62” is used to describe a protein structure element defined by two cysteines (in this case, Cys53 and Cys62). It is not used to describe a polypeptide sequence spanning Cys53 and Cys62. In the latter case, a sequence identifier would have been necessary. Therefore, Applicants respectfully request reconsideration and withdrawal of the objection.

Claim rejections under 35 U.S.C. 112, first paragraph

Claims 28-33, and 54-88 remain rejected under 35 U.S.C. 112, first paragraph, for reasons set forth in the previous Office Action.

Specifically, the Office Action asserts that the specification states in page 10 that the heterologous peptide sequence shares less than 40% identity with a sequence to which it is compared, while the claims do not indicate what sequence the heterologous peptide insert is to be compared to. Thus, the Office Action concludes that a skilled artisan would not know which heterologous peptide insert to select for use in the claimed invention.

Applicants submit that page 10 of the specification defines what is considered a “heterologous peptide” within the meaning of the claimed invention. It simply means that the inserted peptide is substantially dissimilar to the “carrier” protein – the serum albumins. Thus contrary to the Office Action assertion, the pending claims do indicate what sequence the heterologous peptide insert is to be compared with.

If the inserted peptide is not heterologous (for example, if the inserted peptide sequence is identical to the replaced sequences between a particular cysteine loop) when compared to the serum albumin, then it would be essentially recreating the wild-type serum albumin, and thus would not only read on prior art (wild-type serum albumin protein) but also be meaningless for the purpose of the claimed invention. This is analogous to constructing a cDNA library using the lambda phage DNA as vector. Typically, the central portion (the so-called “stuffer” region) of the lambda phage is removed so that heterologous DNAs (such as a cDNA library) can be inserted between the left and the right portions (“arms”) of the lambda phage, which are important for phage replication and packaging. If the inserted DNA is not “heterologous” when compared to the wild-type stuffer region, then the resulting recombinant phage is essentially a wild-type lambda phage, but not a recombinant lambda phage vector encompassing a foreign DNA.

In the instant case, a skilled artisan would understand that the claimed chimeric polypeptide is obtained by replacing one or more of the “stuffer” regions between the defined cysteines with any biologically active polypeptide, provided that the biologically active polypeptide is not serum albumin itself. In other words, the biologically active polypeptide is “heterologous” when compared to serum albumin (SA) as recited in the claims. Thus, the pending claims *do* indicate what sequence

the heterologous peptide insert is to be compared with: they are to be compared with serum albumin to determine if they are less than 40% identical to SA, and thus "heterologous" to SA. Nevertheless, to avoid potential confusion, Applicants have amended claims 28, 54-58, 70-73, and 77-88, and added new claims 93-104 to clarify the subject matter claimed. Applicants submit that there is no narrowing in scope in any respect due to these amendments, as the amended claims merely reflect the interpretation that one of skill in the art would have accorded the claims as originally drafted.

Based on the above argument, Applicants submit that all pending claims meet the requirement of 35 U.S.C. 112, first paragraph. Reconsideration and withdrawal of the rejection is respectfully requested.

### CONCLUSION

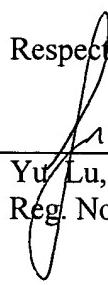
For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims are now in condition for allowance and early notification to this effect is earnestly solicited. Any questions arising from this submission may be directed to the undersigned at (617) 951-7000.

If there are any other fees due in connection with the filing of this submission, please charge the fees to our **Deposit Account No. 18-1945**. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit account.

Respectfully Submitted,

Date: January 22, 2003

**Customer No: 28120**  
Docketing Specialist  
Ropes & Gray  
One International Place  
Boston, MA 02110  
Phone: 617-951-7000  
Fax: 617-951-7050

  
Yu Lu, Ph.D.  
Reg. No. 50,306